



Federal Select Agent Program (FSAP)

When to Report: Using APHIS/CDC Form 3
(Incident Notification and Reporting) 2018
Responsible Official Workshop



August 16, 2018



Agenda

1. **Background/definition**
2. **What is considered a release? (occupational exposure, outside of the primary barriers of the biocontainment area)**
3. **Commonly reported release incidents, associated agents**
4. **Scenarios/examples (consult handout)**

Applicable Regulations

- (a) Upon the discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify DSAT or AgSAS and the appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.
- (b) Upon discovery of the release of an agent or toxin causing **occupational exposure, or release of the select agent or toxin outside of the primary barriers of the biocontainment area**, an individual or entity must immediately notify DSAT or AgSAS.

Definitions

Release

- A release of biological select agent and toxin (BSAT) causing **occupational exposure**, or
- A release of BSAT **outside of the primary barriers of the biocontainment area**

Theft/Loss

- **Theft:** Unauthorized removal of BSAT
- **Loss:** Failure to account for BSAT

Occupational Exposure

- Any reasonably anticipated skin, eye, mucous membrane, parenteral contact, or respiratory aerosol exposure to select agents or toxins that may result from the performance of an employee's duties.
- Includes both direct and proximity exposures
- Does not need to result in a laboratory-acquired infection (LAI) to be reported

Examples of Breaches at Every Biosafety Level (BSL)

□ BSL-2

- Glove tears while working with BSAT
- Spill of BSAT plant material falls to floor outside biological safety cabinet (BSC)

□ BSL-3

- Agar plates inoculated with BSAT dropped during transport from incubator to BSC
- Fermenter hose dislodges and sprays inoculum media

□ BSL-4

- A large gash in the positive pressure encapsulating suit (PPES) while performing necropsies of animals infected with select agent

Discovery of Inactivation Failure

- Entity works with a BSL-3 select agent and routinely inactivates samples for work at lower containment. A researcher in a BSL-2 laboratory notices that laboratory samples are labeled with a different labeling that is routinely used for inactivated samples. Upon further investigation, the researcher realizes that these samples have not been properly inactivated and are still viable. No samples were open, but the samples were unsecured for 3 days before discovery.

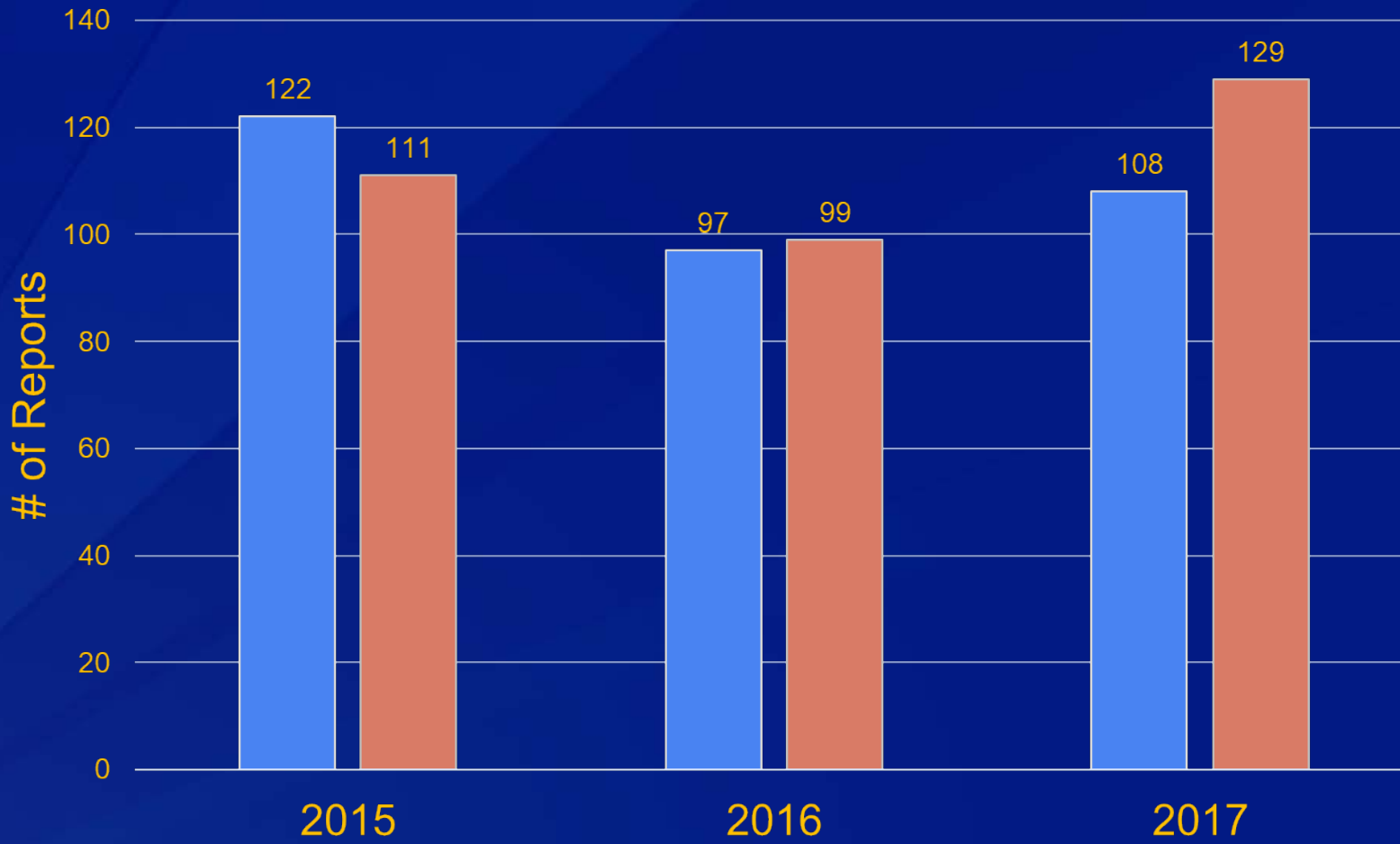
Is this reportable? Why?

Discoveries: How to Report?

- ❑ **Reportable due to:**
 - BSAT samples
 - Samples stored outside registered space

- ❑ **Examples of information to submit**
 - Agent and quantity involved
 - All samples have been accounted for and secured
 - Steps taken to prevent reoccurrence

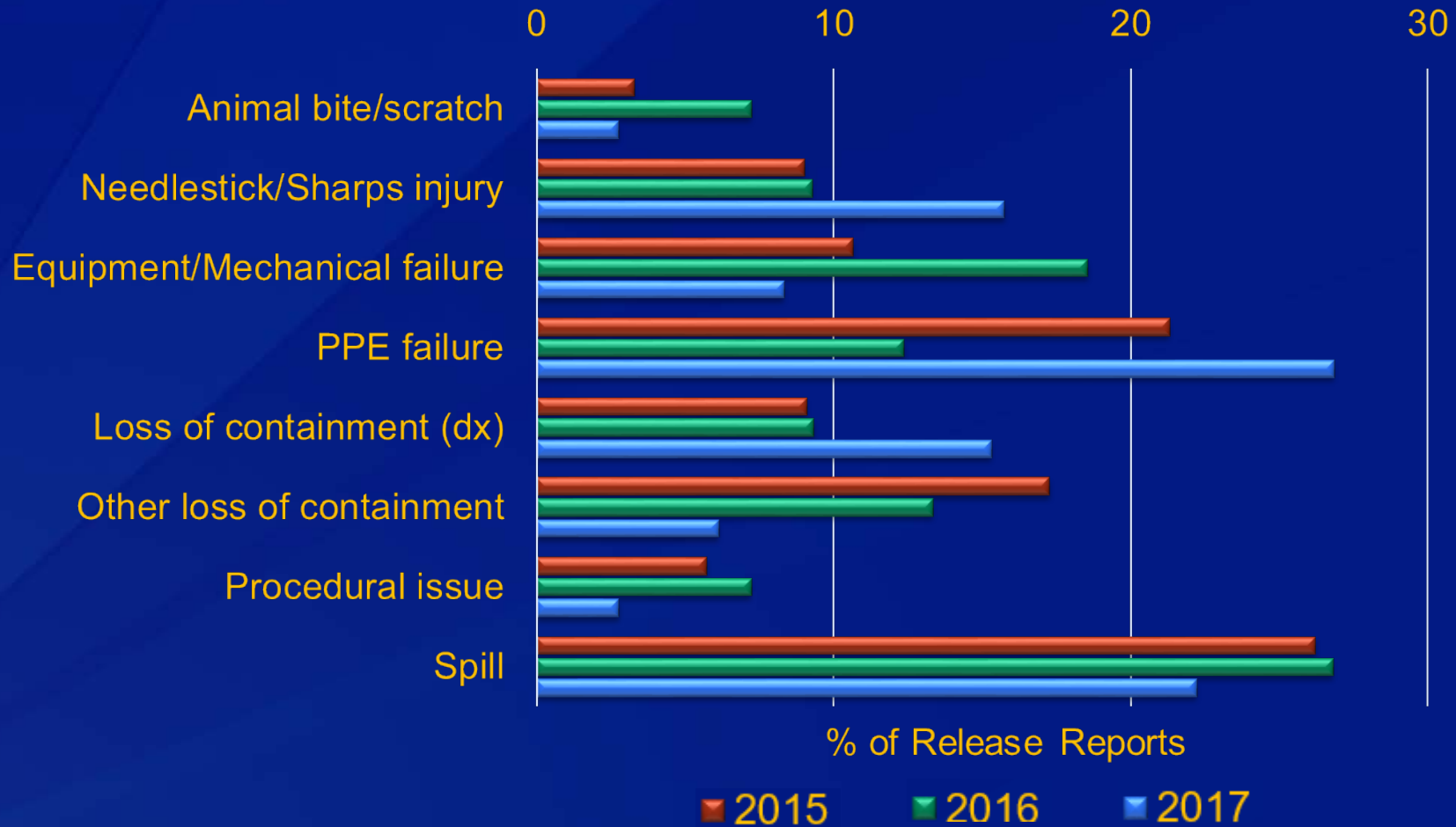
Release Reports, 2015-2017



Total # of reports = 666

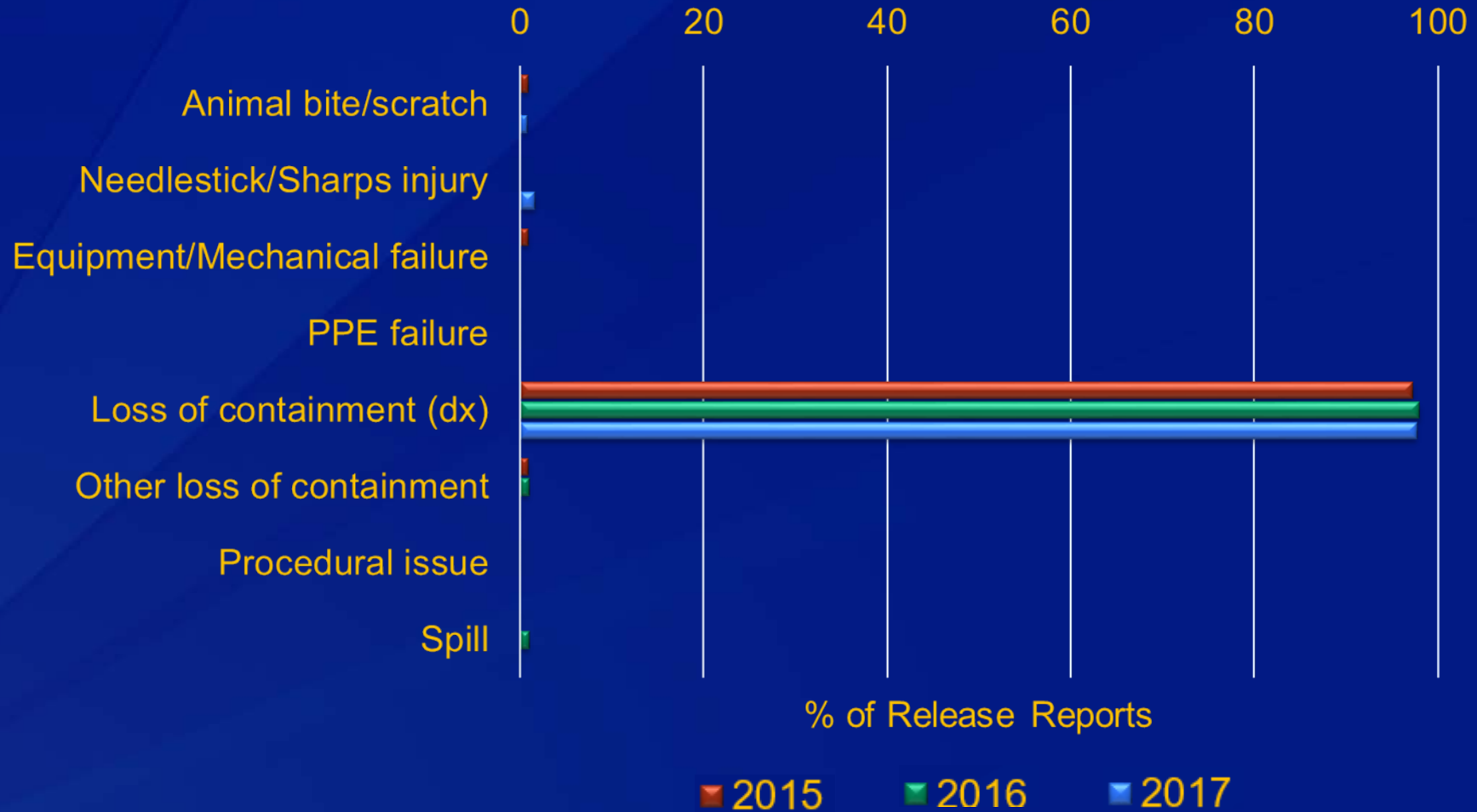
Registered Exempt

Reported Release Events (Registered)



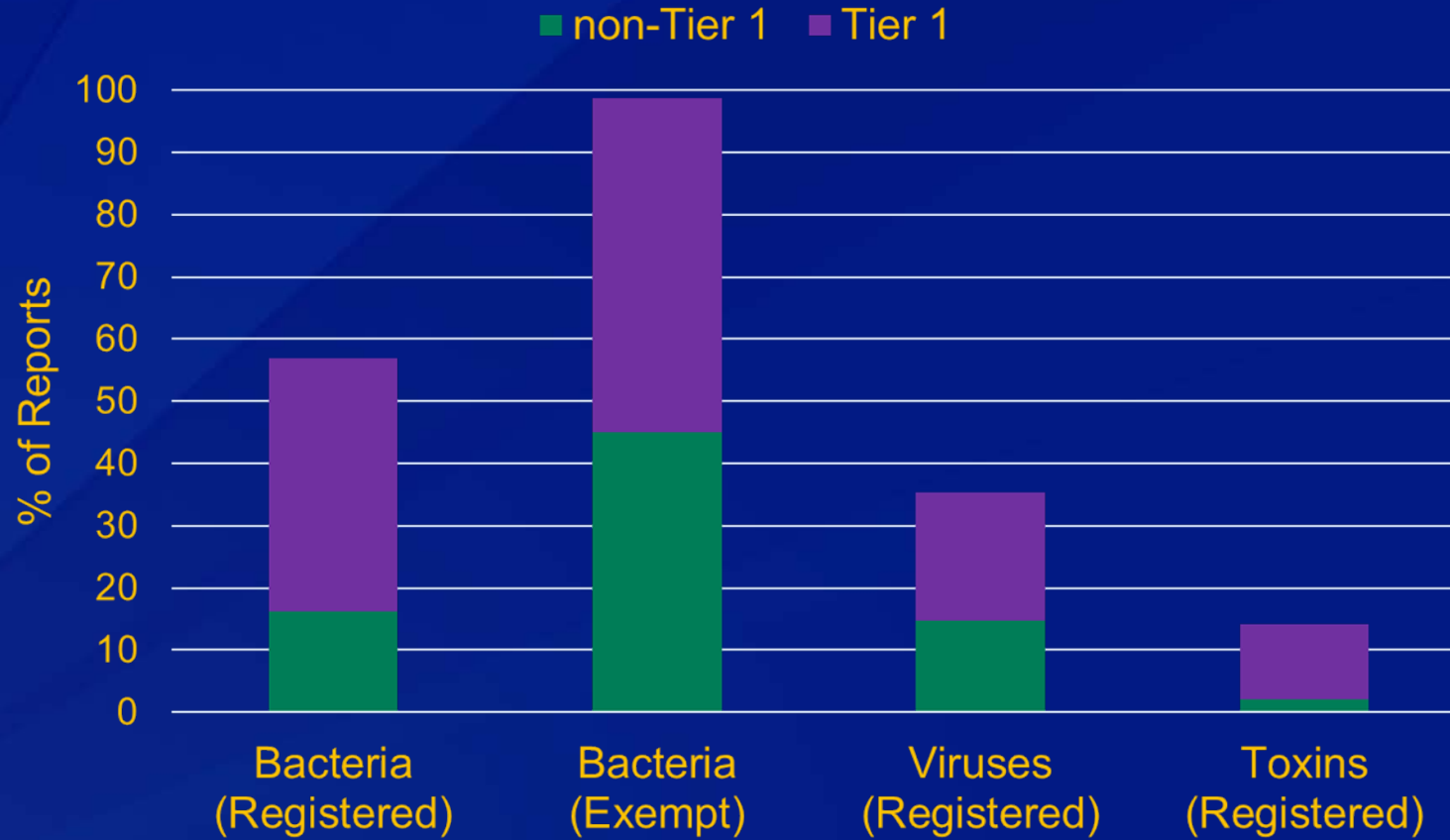
Total # of reports = 327

Reported Release Events (Exempt)



Total # of reports = 339

Types of BSAT reported to DSAT, 2015-2017

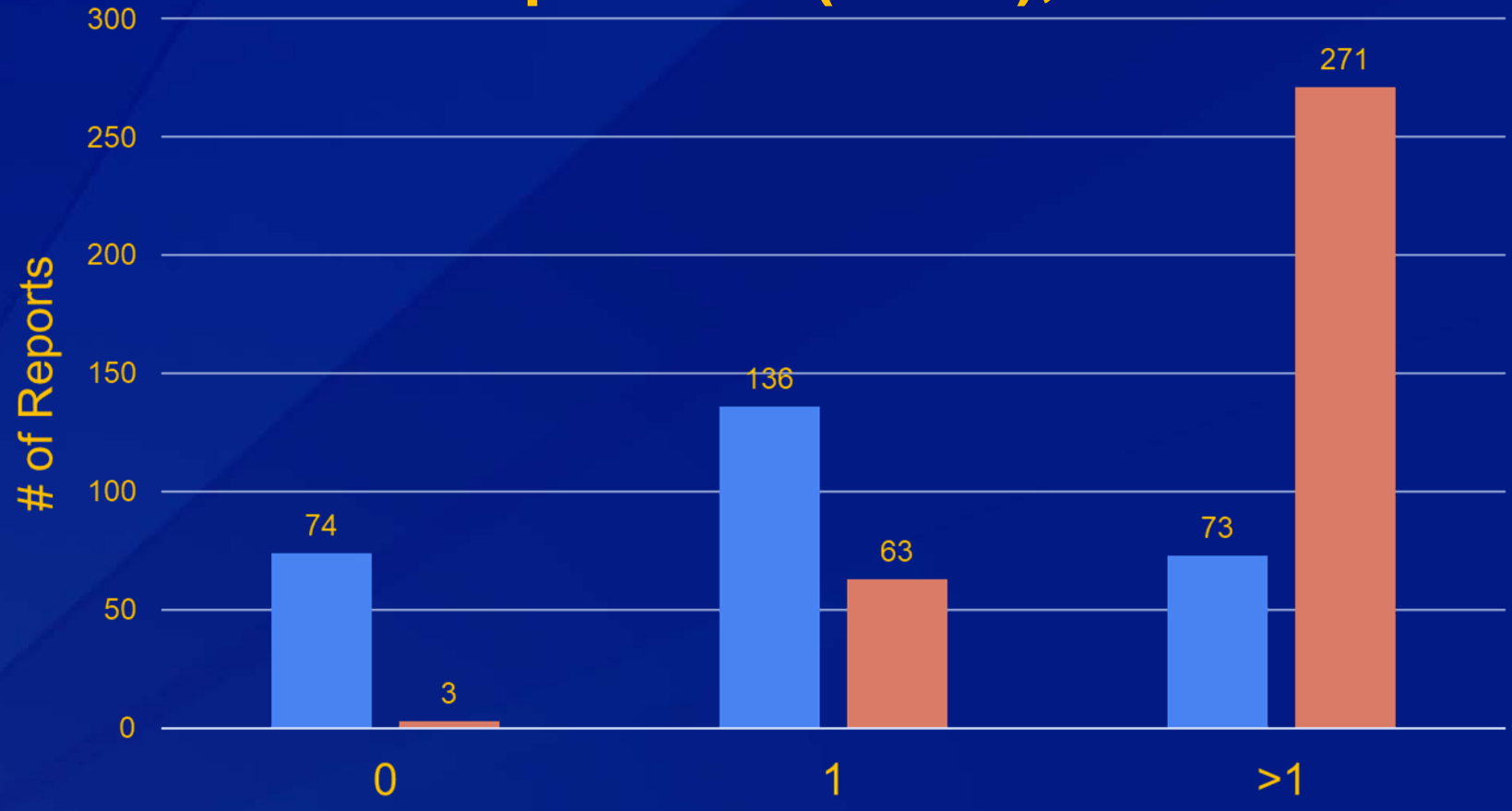


Registered reports = 283

Exempt reports = 337

Total # of reports = 620

Potential Exposures (DSAT), 2015-2017



Number of Potentially Exposed Workers Per Incident

Registered (283) Exempt (337)

Total # of reports = 620

Summary of Preliminary Analysis

1. APHIS/CDC Form 3 Reports submitted to FSAP 2015-2017 = 666 (327 from registered entities, 339 from exempt entities)
2. Bacterial BSAT continue to be the most commonly reported in releases
3. The most common activities reported as leading to release are:
 - loss of containment for exempted entities (98%)
 - spills (25%) and PPE failures (20%) for registered entities
4. A slight majority of DSAT reports with potential exposures are submitted by exempt entities (62%)
5. Single exposure events typically reported to DSAT by registered entities (68%), multiple exposure events by exempt entities (79%)
6. None of the releases reported resulted in illnesses, deaths, or transmission of pathogens outside of laboratories

Scenario 1: Sharps Injuries

A researcher is preparing to inoculate a ferret with Highly Pathogenic Avian Influenza virus for a challenge study. In the process of performing the procedure, the researcher suffers a needle stick injury. Blood is expressed from the wound site and the first aid procedures are performed. The individual is sent to occupational health and placed on fever watch.

Is this reportable? Why?

Scenario 1: Occupational Exposure

- ❑ **Reportable due to:**
 - Occupational exposure due to stick by a needle contaminated with BSAT

- ❑ **Examples of information to submit**
 - Agent and quantity involved
 - Root cause of incident
 - Health status of affected individual
 - Training history of affected individual

Scenario 2: Centrifuge Spill

- A specimen containing *Yersinia pestis* is undergoing centrifugation within a BSC in a BSL-3 laboratory
- The centrifuge safety cup malfunctions, releasing specimen contents within the centrifuge
- Laboratorians in area wear powered, air-purifying respirator (PAPR) during all manipulations of material

Is this reportable? Why

Scenario 2: Centrifuge Spill

- A specimen containing *Yersinia pestis* is undergoing centrifugation within a biological safety cabinet in a BSL-3 laboratory
- The centrifuge safety cup malfunctions, releasing specimen contents within the centrifuge
- Laboratorians in area wear powered, air-purifying respirator (PAPR) during all manipulations of material

No. BSAT within the specimen remained inside primary containment (the BSC).

Discussion

www.selectagents.gov

CDC: Irsat@cdc.gov or 404-718-2000

APHIS: AgSAS@aphis.usda.gov or
301-851-3300 option 3 (voice only)

